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GB04/4385

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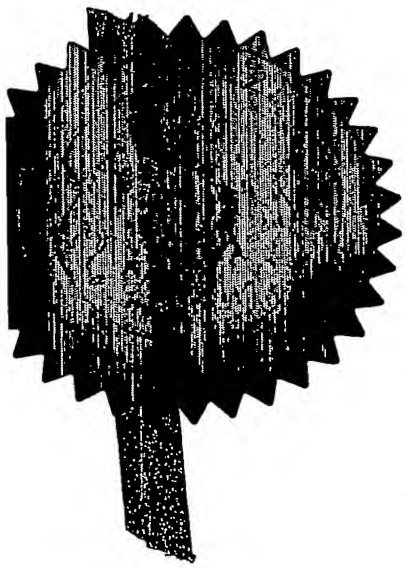

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Patents Form 1/77

The Patent Office

1/77

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

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15 OCT 2003

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1. Your reference: IT/LT/N14717

160CT03 E844893-5 D02136
P01/7700 0.00-0324173.4

2. Patent application number *(The Patent Office will fill this part)*: 0324173.4

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Anson Medical Ltd
67 Milton Park
Nr. Abingdon
Oxfordshire OX14 4RX, United Kingdom

Patents ADP number *(if you know it)*: 7917552001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

Flexible Delivery System

5. Name of your agent *(if you have one)*: Williams Powell

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*:

Morley House, 26-30 Holborn Viaduct
London
EC1A 2BP

Patents ADP number *(if you know it)*: 5830310001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country *(if you know it)*	Priority application number	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application.

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(answer 'Yes if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

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9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	3
Claim(s)	1 DL
Abstract	~~0~~
Drawing(s)	3 ~~0~~ 3

10. If you are filing one of the following, state how many against each item.

Priority documents	None
Translations of priority documents	None
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	None
Request for preliminary examination and search *(Patents Form 9/77)*	None
Request for substantive examination *(Patents Form 10/77)*	None
Any other documents *(please specify)*	None

11. I/we request the grant of a patent on the basis of this application.

Signature [signature] Date 15 October 2003

12. Name and daytime telephone number of person to contact in the United Kingdom: Mr Lee Anderson 020 7936 3300

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Notes

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Flexible Delivery System

The present application relates to flexible tubular or catheter-based delivery systems for introducing implants into patients through a remote point of entry. More particularly, it relates to a method of improving delivery systems that are used to place stent grafts into arteries, most commonly using an entry point at the iliac or common femoral artery and deploying the stent graft within the aorta.

Current stent grafts designed for implantation into the aorta are typically radially compacted by a factor of 4 so that a 28mm diameter graft will require a delivery system with a diameter of the order of 7mm.

While this diameter of delivery system is adequately small to permit surgery through minor incisions, it is difficult to achieve the degree of flexibility that is required to pass through the vascular tree to the delivery site.

Many stent graft delivery systems, such as the Zenith (TM) from Cook Inc, the Talent (TM) from Medtronic Inc and the Anneurx (TM) also from Medtronic Inc involve two key components: an outer sheath and an inner 'retainer' rod. In use, the stent graft is compacted and inserted into the end of the sheath and the retainer rod is inserted from the far end of the sheath until the retainer rod contacts the stent graft. By various means, the sheath and its contents are introduced through the vascular tree until that part of the sheath containing the stent graft is located at the desired landing site for the stent graft. The sheath is then pulled slowly backwards, but the stent graft is retained in position by the retainer rod. As the sheath is pulled further back, the stent-graft begins to emerge from the open end of the sheath and deployment is complete when the sheath has been pulled back to the point where its end is level with the end of the retainer rod.

In practice, the retainer rod must be made of a material which is sufficiently flexible to allow the delivery system to follow the curves of the arterial tree. However, the forces involved in deploying stent grafts can be quite high and the retainer rod may be axially compressed as the stent graft is being deployed. Such compression is undesirable because it reduces the accuracy of deployment and can be the cause of radial expansion of the retainer rod. This radial expansion can lock the retainer rod in the sheath, preventing further deployment of the device.

A further requirement of the retainer rod is that it should be able to transmit twisting of the handle of the delivery system through to the stent graft. In a successful delivery system, the position of the device needs to be accurately controlled in rotation so that features of the stent graft can be made to align with anatomy. When the retainer rod is too soft or elastic, control of the device from the handle is imprecise, making it difficult, for instance, to ensure that paired legs of a bifurcated graft lie in a plane parallel to their target vessels.

Thus the requirement for flexibility suggests soft materials for the retainer rod, whereas the requirements of torsion control and incompressibility suggest employing a stiff material.

In accordance with the invention, one partial solution to these contradictory requirements is to employ a hard material for the retainer rod, but to cut it into short segments which are free to articulate against each other.

This solution is illustrated in Figure 1 in which two segments of retainer rod are shown, articulated against each other to provide a flexible, incompressible retainer rod.

The solution relies upon the presence of the outer sheath to prevent the segments from migrating and is further compromised by the complete absence of a mechanism for transmitting torque from one

segment to the next. It is obvious that a practical device will require a multiplicity of segments of the type illustrated in Figure 1.

A further problem with this approach is that the composite retainer rod lengthens as it is flexed making the approach impractical for applications requiring high levels of flexibility.

An improvement over this first design is illustrated in Figure 2 which employ segments of a hard material as before but in which abutting ends of the segments are chamfered so that the degree of articulation can be increased before the retainer rod lengthens.

Having established the principles illustrated in Figures 1 and 2 in which the retainer rod has a segmental construction and in which the abutting surfaces are modified to improve the characteristics of the ensemble it is possible to devise further modifications to the abutting surfaces to provide additional features.

Figure 3 illustrates a practical design of segment which employs the characteristics shown in Figures 1 and 2 but which includes additional features to transmit torque, to allow additional longitudinal structures and to maximise the smoothness of the outer sheath when flexed.

Ideally, the practical design for a 21 French (7 mm diameter) delivery system employs segments which are 6 mm in diameter and 10.5 mm long. These dimensions can be scaled larger or smaller to cater for larger or smaller delivery systems: a 10 French system will employ segments approximately 3 mm in diameter and a 50 French system will require segments 15 mm in diameter. The ratio of length to diameter of the segments is 1.75 : 1 and workable designs can be made where this ratio is increased to 5 : 1 although manufacturing is less demanding and flexibility is improved if the ratio is limited to between 1.5 : 1 and 3 : 1. If some reduction in strength is acceptable, the ratio between the length and the diameter can be reduced to 1 : 1. It is inadvisable to make the segments shorter than their width because they are more inclined to 'rock' in the sheath and to cause jamming.

Ideally, the segment is designed to be easily manufactured and injection moulding is a convenient technique to use, employing an appropriately hard and sterilisable plastic. Preferably, a single segment is designed so that features on a first abutting surface correspond with inverse features on the second abutting surface. It is possible to design segments which must be combined in pairs, although this is less convenient. With a single segment, multiple units can be stacked to form a long, rod-like structure, while each segment can be manufactured from a single injection mould tool.

Preferably, each segment has a central axial hole that allows a guide wire and surrounding structures to pass therethrough.

In some applications, there are advantages in assembling the 'retainer rod' from in groups of segments so that, for instance, the group of segments nearest the handle provide less flexibility than those at the tip.

Ideally the abutting surfaces have part spherical ends (5 & 9) to allow the greatest degree of flexion between adjacent segments.

In order to transfer torque effectively from one segment to another, at least one lateral process (6) is incorporated into the segment so that it will engage a corresponding elongated opening (10) in the abutting segment.

The walls of the segment are slightly barrel-shaped (8) so that even under extreme degrees of flexion the profile of the sheath over the segments is smooth and continuous.

When lateral processes are employed to transmit torque to adjacent segments it is possible to introduce additional lumens, off the central axis of the segment. (7) is a groove which permits one such off-axis lumen to be employed and it will be apparent to the skilled person that additional grooves can be placed at other points around the circumference of the segment.

An illustration of two adjacent segments interconnecting is shown in Figure 4. A practical device will have many more segments than those illustrated, a typical delivery system requiring between 15 and 80 of the segments described, depending on the length of the device.

At either end of the retainer rod, modified segments, or end segments, can be used so that an effective interface is made between the segmental retainer rod and the handle components at one end, and the segmental retainer rod and the implant at the second end. In either case, the end segments will be designed to match the handle and implant components but it is desirable that those aspects of the end segments which interface with the segmental retainer rod retain all the mating features so that torque and lumens can be transmitted through to other components and to ensure that flexibility is retained.

FIGURES

Figure 1 illustrates a basic segmental retainer rod comprising simple, plane-faced cylindrical segments (1 & 2).

Figure 2 illustrates an improved version of Figure 1 in which the abutting faces (3 & 4) have been chamfered to enable a greater degree of flexion to take place without a significant change in length occurring.

Figure 3 illustrates a practical design of segment suitable for injection moulding. It comprises a ball end (5) which engages the ball socket (9) of the adjacent segment. Lateral process (6) transmits torque to opening (10) in the adjacent segment. Slot (7) permits a lumen to be attached to the segment of the central axis of the device.

Figure 4 illustrates two segments of the type shown in Figure (3) abutting as they would in a practical device. The illustration shows the two components in a flexed state.

Claims

1. A delivery system for a medical implant wherein a central rod is used to push the implant from the end of the tube and in which the central rod is made from a multiplicity of short segments.

2. A system as in claim 1 in which the abutting faces are part-spherical.

3. A system as in claim 1 which has at least one lateral process that will engage with an opening in an adjacent segment.

4. A system as in claim 1 with a central hole passing through its body along its axis.

5. A system as in claim 1 with at least one longitudinal hole or slot parallel to but displaced from the axis of the segment.

6. A system as in claim 1 where the ratio of the length to the diameter of the segment lies in the range 1 : 1 to 5 : 1.

7. A system as in claim 1 where the ratio of the length to the diameter of the segment lies in the range 1.5 : 1 to 3 : 1.

8. A system as in claim 1 where the diameter of the segment lies in the range 3 to 15 mm.

9. A system as in claim 1 in which the 2nd abutting face is the inverse of the 1st abutting face.

10. A system as in claim 1 where the central rod is composed of at least two groups of segments, the segments of the first group having different properties from the segments of the at least second group.

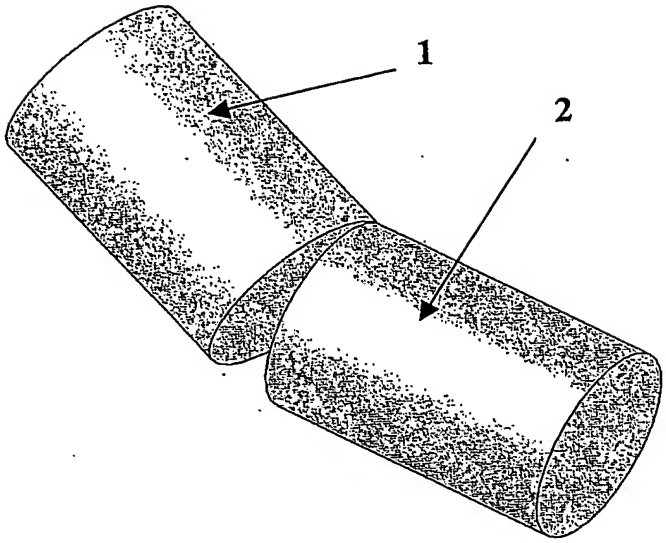

Figure 1

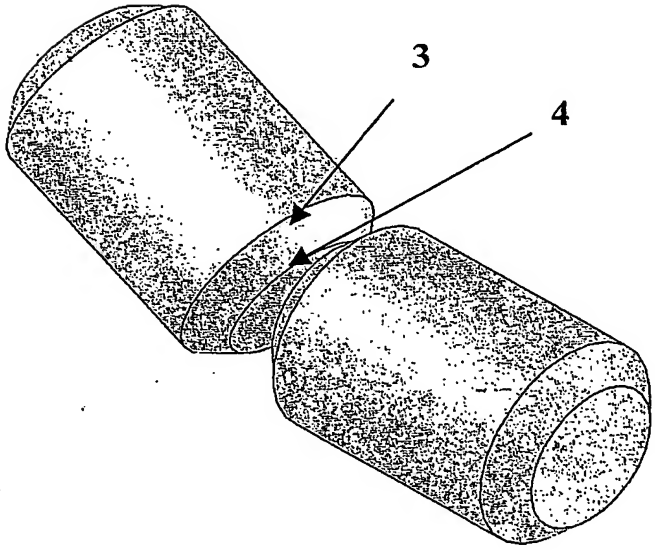

Figure 2

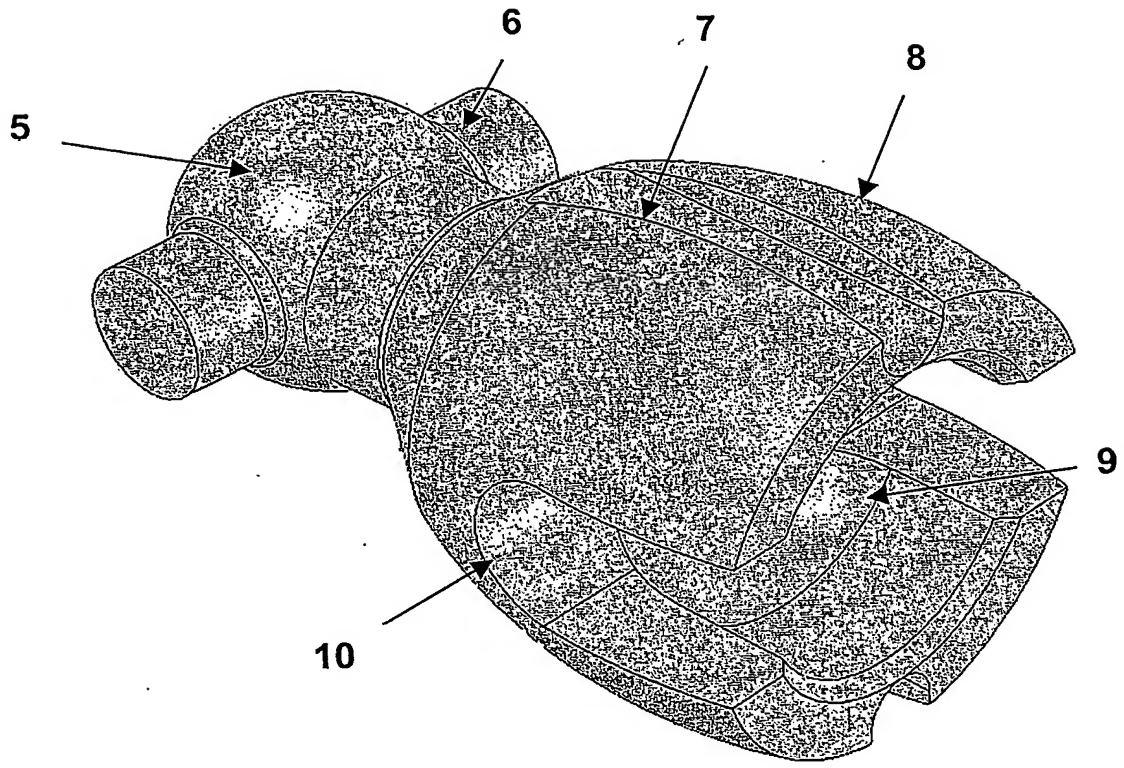

Figure 3

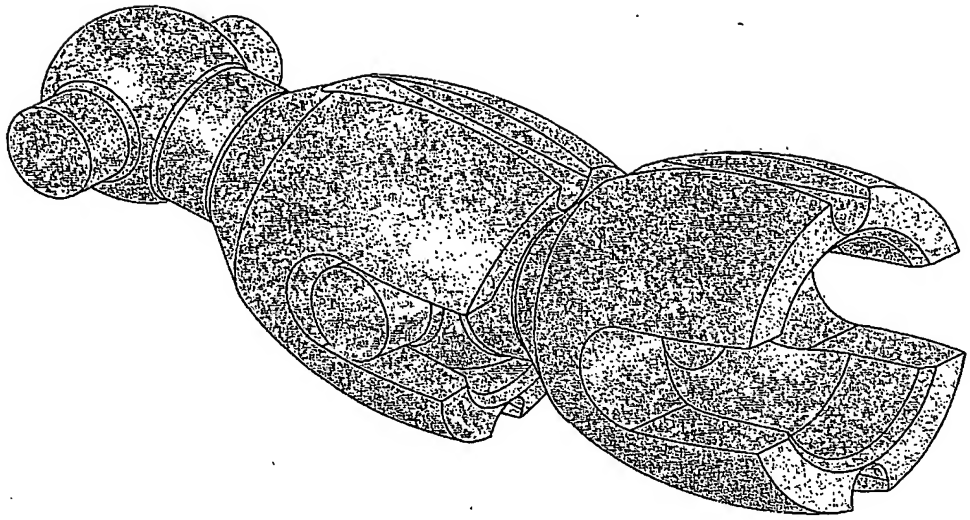

Figure 4